MGuard Embolic Protection Stent – The Importance of Thrombus Management in ST-elevation Myocardial Infarction Primary Percutaneous Coronary Intervention

Proceedings of STEMI symposium at EuroPCR on 20–23rd May 2014 in Paris

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Abstract

Distal embolisation of atherothrombotic material is a frequent consequence of percutaneous coronary intervention (PCI) in ST-elevation myocardial infarction (STEMI). This causes microvascular occlusions, leading to a further reduction in myocardial reperfusion. The MGuard™ embolic protection stent (EPS) features a unique polymer micronet mesh coating. When used in acute STEMI, the MGuard EPS shows significant improvement in myocardial flow and ST resolution, even in complicated clinical cases vs the standard approach with conventional bare metal or drug-eluting stents. Data from the andomised Safety and Efficacy Study of MGuard Stent After a Heart Attack (MASTER II) trial and from a real-life registry have shown the efficacy and safety of the MGuard in primary PCI. This report of the proceedings of a symposium at EuroPCR, 20–23 May 2014, Paris, France, discussed clinical trial data, as well as a number of clinical cases, illustrating the utility of the MGuard EPS in difficult situations.

Keywords

ST-elevation myocardial infarction, percutaneous coronary intervention, distal thromboembolism, stent, distal embolisation, STEMI, thrombus, thrombus loaded lesion, Acute myocardial infarction, target lesion, mesh

Disclosure: Dr Lotan is Medical Director for InspireMD; Dr Abizaid, Dr Henriques, Dr Dudek, Dr Costa, Dr Fajadet, Dr Kornowski and Dr Amoroso have no conflicts of interest to declare.

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Embolisation of atherothrombotic material is a common occurrence during percutaneous coronary intervention (PCI) in ST-elevation myocardial infarction (STEMI). This may lead to distal vessel occlusion resulting in impaired myocardial perfusion, which is associated with larger infarct size, incomplete ST resolution and increased mortality. Unfortunately, there is a lack of significant adjunctive devices to protect the microcirculation. A symposium was sponsored by Inspire MD and chaired by Alexandre Abizaid, Institute Dante Pazzanese de Cardiologia (Sao Paulo, Brazil), and Jean Fajadet, Clinique Patteur, (Toulouse, France). These presentations aimed to discuss the importance of thrombus management in PCI for STEMI patients, to give an update of relevant clinical data on the performance of the MGuard™ stent in STEMI patients and to present real life examples on how this device selection can influence the outcome in STEMI patients. ■

Therapeutic Alternatives for Intracoronary Thrombus – MASTER Results in Perspective

Alexandre Abizaid[1] and Chaim Lotan[2]

1. Dante Pazzanese Institute, Sao Paulo, Brazil; 2. Hadassah-Hebrew University Hospital, Jerusalem, Israel

Dr Abizaid began by emphasising the need for therapeutic alternatives to avoid distal thromboembolism (embolisation) during highly thrombotic situations such as STEMI. The Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction

Figure 1: The MGuard™ Prime Embolic Protection Stent

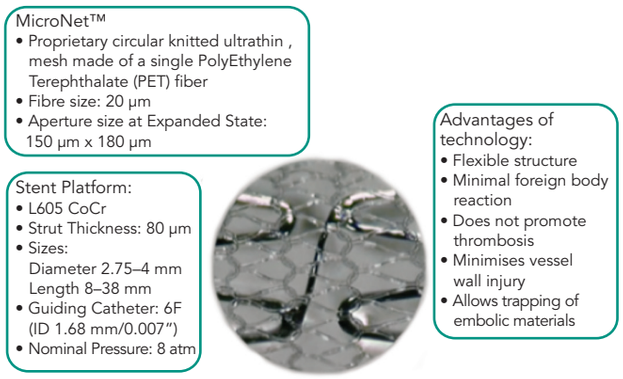


Figure 2: Optical Coherence Tomography of MGuard™ in Acute Myocardial Infarction Showing Thrombus Entrapment Behind the Protective Net

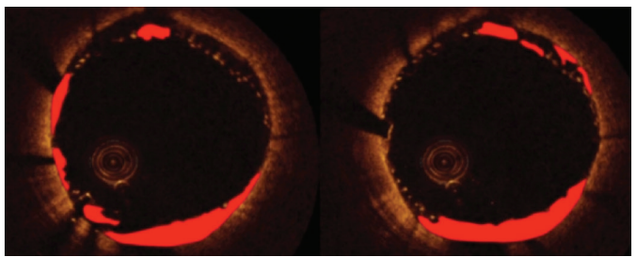
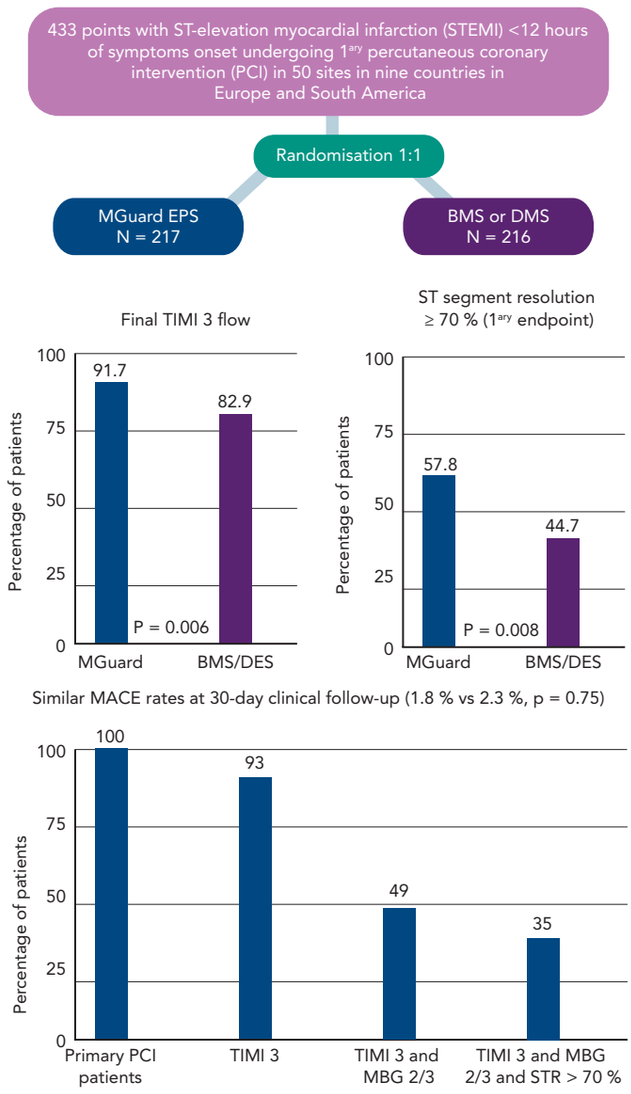


Figure 3: The MASTER Trial



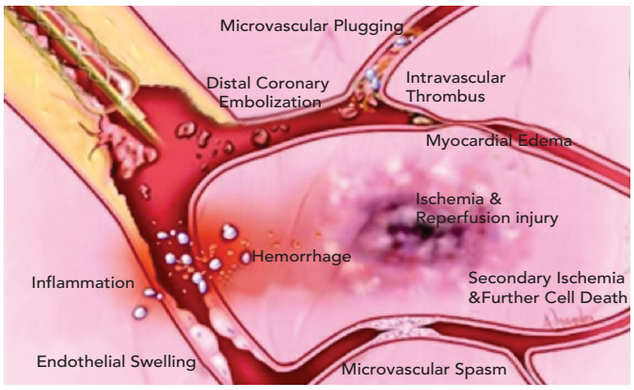
Study (TAPAS), prospective randomised trial, aimed to determine whether aspiration of thrombotic material before stent implantation of the infarct-related coronary artery resulted in improved myocardial perfusion compared with conventional primary PCI.[1] Results showed a reduction in all-cause mortality at 30 days. However, the Thrombus Aspiration during ST-segment Elevation myocardial infarction (TASTE) study (n= 7244) found that routine thrombus aspiration before PCI as compared with PCI alone did not result in a reduction in 30-day mortality.[2] Even if aspiration is good, embolisation remains an ongoing issue.

The MGuard™ Embolic Protection Stent (EPS) is a novel device. The EPS has evolved from the stainless steel MGuard to the L605 cobalt chromium MGuard Prime, both featuring a polyethylene terephthalate (PET) mesh with 150–180 µm aperture size, preventing the prolapse of thrombus and potential distal embolisation (see *Figure 1*). Case reports in patients with STEMI undergoing primary PCI have demonstrated the ability of the MGuard EPS to capture and contain ('jail') thrombus and atheroma behind its net, thereby preventing distal embolisation (see *Figure 2*).

The MGuard for Acute ST Elevation Reperfusion (MASTER) trial recruited 432 patients with symptoms consistent with STEMI within 12 hours of symptom onset, at 50 sites in nine countries.[3] Participants were randomised to PCI with bare metal stent (BMS) or drug-eluting stent (DES), (n=216) or to PCI with MGuard (n=217). Follow-up was at 30 days, six months and one year. The primary endpoint was ST-segment resolution at 60–90 minutes. Other inclusion criteria were ≥2 mm of ST-segment elevation in ≥2 contiguous leads and PCI of a single de novo lesion with reference vessel diameter (RVD) ≥3.0 to ≤4.0 mm and length ≤33 mm (capable of being covered by a single study stent). The primary endpoint of post-procedure complete (≥70 %) ST-segment resolution was significantly higher in the MGuard stent group compared with the control group (57.8 % vs 44.7 %; difference: 13.2 %; 95 % confidence interval: 3.1 % to 23.3 %; p=0.008; see *Figure 3*). The MGuard EPS also showed superior rates of thrombolysis in myocardial infarction (TIMI) 3 flow (91.7 % vs 82.9 %, p = 0.006).

Major adverse cardiac events (1.8 % vs 2.3 %, p=0.75) at 30 days were not significantly different between the two groups. Although the study was not powered for mortality, a trend in favour of the MGuard EPS was observed (0 % vs 1.9 %, p=0.06). A substudy, in which patients underwent magnetic resonance imaging (MRI) at five days, showed a trend towards smaller infarct size measured by delayed enhancement with the MGuard EPS.[4] At 12 months, the trend towards reduced cardiac mortality with the MGuard EPS was still seen but again did not reach statistical significance (1.0 % vs 3.3 %, p=0.092).[5] No significant differences in reinfarction or stent thrombosis were seen at 12 months between the MGuard EPS and control groups. The 12-month target lesion revascularisation (TLR) rate and 13-month late loss and binary restenosis rates for the MGuard EPS was higher

Figure 4: Pathophysiology of no Reflow in Primary Percutaneous Coronary Intervention



Source: Abbate et al., 2008.[11]

than the in control group but comparable to other BMS cohorts such as in the large Harmonising Outcomes with RevasculariZatiON and Stents in Acute Myocardial Infarction (HORIZON) trial.[4] Another subanalysis divided patients into two groups according to the measured volume of thrombus (≤ or >30 mm^2). In the small thrombus group, complete resolution of ST-elevation was achieved in 66.2 % of the MGuard group vs 44.9 % of the control (p=0.02).[6] In the large thrombus group, complete resolution was achieved in 54.7 % of the MGuard group vs 42.3 % of the control (p=0.02). These data suggest that the device may be successfully employed in patients with large thrombus burden.

In conclusion, among patients with STEMI undergoing emergent PCI, the MGuard EPS resulted in superior rates of restored flow (TIMI 3) and complete resolution of ST elevation, with a trend to reduced mortality compared with control groups. ■

The Enemy of Primary PCI

Chaim Lotan

Hadassah University Hospital, Jerusalem, Israel

Dr Chaim Lotan, Hadassah Medical Center (Jerusalem, Israel) discussed the clinical challenge of 'no-reflow' in primary PCI. Angioplasty is associated with improved epicardial flow, greater reperfusion rate and improved survival, when compared with thrombolytic therapy.[7] However, despite TIMI 3 flow, optimal myocardial reperfusion is probably only achieved in one third of patients.[8] This phenomenon is known as slow flow or no-reflow and characterised by 'slow flow' in the affected vessel and lack of contrast uptake ('blush') by the subtended myocardium, which is associated with a poor prognosis.[9,10] The pathophysiology of no reflow is described in *Figure 4*.[11] It is a multifactorial condition and is caused by four interacting mechanisms: ischaemic injury, reperfusion injury, distal embolisation and susceptibility of the microcirculation to injury.[12] The timing of distal embolisation varies and can affect outcomes: distal embolisation before PCI is visible in 5 % of angiograms before PCI and in 15–17% after PCI.[13,14] Thrombus composition and size is also related to outcomes. Fresh thrombus that can be aspirated typically only represents 30 % of the total thrombus load. The plaque represents 24 % and organised thrombus accounts for 47 %.[15] Furthermore, angiography underestimates residual thrombus after aspiration; this can be demonstrated by optical coherence tomography (OCT).[16]

The MGuard EPS prevents post stenting protrusion of the remaining thrombus, commonly seen with conventional stent, as the micronet seals ("jails") the thrombus against the vessel wall. ■

STEMI Demonstrative Cases 1 Successful and Unsuccessful Techniques?

Ran Kornowski

Rabin Medical Center, Petach Tikva, Israel

Dr Ran Kornowski, Rabin Medical Center (Tel Aviv, Israel), began by stating that as of 2013, 56 % of STEMI in Israel still received aspiration, and 46 % had glycoprotein (GP) IIb/IIIa infusion during STEMI. Only around 10 % received MGuard EPS implantation during STEMI. He then presented a case of an 88-year-old man with hypertension, chronic obstructive pulmonary disease (COPD) and renal dysfunction who presented with an extensive anterior wall STEMI. The duration of chest pain before admission was 1.5 hours and door-to-balloon time was 42 minutes. Echocardiography on admission showed moderate left ventricle (LV) dysfunction, and the patient was immediately taken to the catheterisation laboratory, where he received primary PCI of an occluded mid-left anterior descending (LAD) artery with a large thrombus burden. After wiring, a large amount of thrombus was seen on the angiogram. After aspiration, a significant amount of thrombus remained without restoration of normal flow even after an additional aspiration attempt. An MGuard Prime EPS (4 x 19 mm) was therefore implanted with immediate improvement in flow after deployment. After 30s, a TIMI 2/3 flow was achieved. Prior to discharge, echocardiography showed a substantial improvement in LV function.

In conclusion, this real-life case has demonstrated the utility of an MGuard EPS in an elderly patient with anterior STEMI caused by LAD occlusion by a large coronary thrombus, with limited efficacy of thrombus aspiration and anti-thrombotic regimen. ■

STEMI Demonstrative Cases 2
MGuard Prime EPS Optical Frequency Domain Imaging (Insights) – STEMI

Yaron Almagor,[1] Carlos Cafri[2] and Ben Gurion[3]

1. Shaare Zedek Medical Center, Jerusalem, Israel; 2: Soroka University Medical Center; 3. University of Negev Beer Sheva, Israel

Dr Yaron Almagor, Shaare Zedek Medical Center (Jerusalem, Israel), presented a case that illustrated the effectiveness of the MGuard Prime in acute MI. The case was of acute anterior wall STEMI with total occlusion of the LAD. After a small balloon, the thrombus could clearly be seen using coronary OCT. Immediately after implantation of an MGuard Prime EPS, excellent reperfusion was achieved. OCT showed no thrombus protrusion. The MGuard Prime EPS showed excellent stent apposition by OCT with open side branches post stenting. He ended his presentation stating: "I never expected a result like this."

Dr Carlos Cafri, Soroka University Medical Center and Ben Gurion University of Negev (Beer Sheva, Israel), presented a case of a 58 year-old man with diabetes who had been admitted after threee hours of chest pain. An electrocardiogram (ECG) revealed ST-elevation in inferior wall leads. Angiography showed occlusion in the right coronary artery (RCA). Manual thrombus aspiration resulted in restoration of TIMI 3 flow but considerable stenosis and thrombus remained visible while the patient was still experiencing chest pain. An MGuard Prime EPS (3.5 x 18 mm) was implanted, without predilatation to avoid high pressure during implantation; a long stent was chosen to avoid dislodgement of thrombus at the distal end of the stent. The outcomes were excellent. Dr Cafri concluded that the MGuard Prime EPS allows appropriate management of seemingly impossible thrombotic situations. ■

STEMI Demonstrative Cases 3
STEMI and Small Aneurysm

Graham Cassel

Milpark Hospital, Johannesburg, South Africa

Dr Graham Cassel of Milpark Hospital, Johannesburg, South Africa, presented a case of a 52 year-old male with hypertension and hypercholesteraemia, who presented one hour after the onset of severe chest pain with inferior STEMI. Angiography showed a totally occluded RCA, as well as severe stenosis in the LAD and circumflex (CX) arteries. Following thrombus aspiration, TIMI 3 flow was achieved but an aneurysm was detected in the middle of the stenosis of the RCA. An MGuard Prime EPS (4 x 28 mm) was implanted, resulting in exclusion of the aneurysm and excellent distal flow. Two weeks later, when the LAD and CX were treated percutaneously, the MGuard Prime EPS still showed excellent angiographic results. ■

STEMI Demonstrative Cases 4
How Could I Treat a Bifurcation With High Thrombus Burden Despite Exhaustive Aspiration?

Rafael Romaguera

Bellvitge University Hospital, Barcelona, Spain

Dr Rafael Romaguera of Bellvitge University Hospital, Spain, presented a case of a 49-year-old male smoker admitted with 13 hours of ongoing chest pain with signs of an inferior STEMI on the ECG. Aspirin (250 mg), clopidogrel (600 mg) and unfractionated heparin (UFH; 100 UI/kg) were administered. Coronary angiography revealed an occlusion in the distal segment of the RCA, with a large thrombus at a bifurcation. Eight rounds of aspiration were performed with two different 6F catheters. An additional wire was advanced to perform aspiration of the posterior descending artery (PDA). However, these interventions failed to restore flow. After implantation of an MGuard (2.5 x 28 mm) EPS, restoration of flow was achieved. Subsequently, side branch occlusion was seen, possibly due to mechanical obstruction by the stent platform and net, or possibly due to thrombus being squeezed from the main vessel into the side branch. The PDA was rewired across the stent with an intermediate stiffness coronary wire. However, the operator was unable to advance the device through the mesh because of the angle and lack of support of a 6 Fr catheter. A 1.5 x 6 mm balloon was then advanced through an extension catheter and dilated. However, this failed to restore full flow so T-stenting with a BMS was attempted. This corrected the flow and the patient's chest pain resolved despite a very long ischaemic time. The patient was discharged a few days later with dual antiplatelet therapy (DAPT). Concerns were

raised about the impact of the T stenting solution combined a regular BMS and an MGuard with its dedicated mesh. Angiographic follow-up after six weeks showed TIMI 3 flow in both vessels without signs of restenosis. An OCT showed that the bifurcation was patent, with good apposition of the stent and strut coverage. Also, an improvement of LV function was observed. In conclusion, MGuard EPS implantation at a complex bifurcation lesion was feasible and improved myocardial perfusion. Importantly, the side branch could be accessed and treated even after MGuard EPS implantation in the main vessel without compromising the acute and long-term results. ■

STEMI Demonstrative Cases 5 Acute Anterior Wall Infarction

Maarten Vink

Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands

Dr Maarten Vink, Onze Lieve Vrouwe Gasthuis (Amsterdam, The Netherlands), presented a case of a 68-year-old female with no cardiac history, although she had risk factors including smoking and family history. She was admitted following the acute onset of chest pain and received heparin, aspirin and prasugrel in the ambulance. Angiography revealed a long thrombus-containing lesion in the ostium of the LAD with impairment of flow (TIMI 1). Wiring of the lesion improved the flow and since it was important not to dislodge the thrombus, aspiration was not chosen nor was pre-dilatation. Instead, direct stenting was performed with an MGuard Prime EPS (3.5 x 28 mm); a long stent was required to cover the thrombus. Immediately afterwards, TIMI 3 flow was achieved and the patient was symptom-free with only a minimal rise in cardiac enzymes. An ECG revealed complete ST resolution after the procedure and no apparent wall motion abnormalities at three months follow up. Dr Vink concluded that there is no need for thrombus aspiration and/or pre-dilatation if the TIMI flow is ≥1 and that the MGuard may allow achievement of fast restoration of flow with minimal use of equipment. ■

What is the MGuard Role in Primary PCI Today?

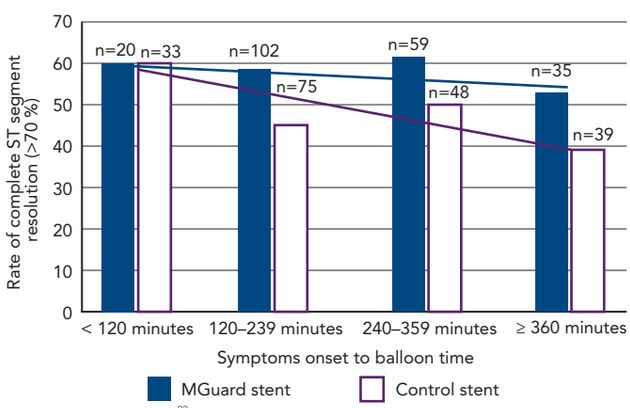
Dariusz Dudek

Jagiellonian University, Krakow, Poland

Dr Dariusz Dudek, Jagiellonian University (Krakow, Poland) began by presenting data that show that primary PCI caused a substantial decline of in-hospital mortality due to STEMI between 1960 and 2000.[17] However, since then, STEMI mortality has plateaued at around 5 %, suggesting that additional strategies are required.[18] The key goals of primary PCI are to restore epicardial flow; to prevent distal embolisation and no reflow; to improve myocardial reperfusion and to reduce infarct size. Recent studies suggest that DES are more beneficial than BMS in STEMI in terms of mortality.[19] However, optimal microvascular/myocardial perfusion (TIMI 3 and myocardial blush 2/3) is often not achieved in PCI,[8] with detrimental effects on long-term mortality.[20]

Clinical data using the MGuard was first published in 2010.[21] At that time, data from the MAGICAL trial in Krakow showed that the use of MGuard EPS implantation during primary PCI for STEMI is safe and is associated with excellent results in terms of myocardial reperfusion parameters. Importantly, no thrombus protrusion was seen with MGuard. The early safety and efficacy of the MGuard stent was maintained during the long-term follow-up (mean follow-up of 38.7 ± 3.1 months).[22] In a substudy of the MASTER trial, patients were divided into two groups. Those with symptom onset to balloon time ≤3 hours when thrombus is fresh, and >3 hours. Later presentation of MI showed a bigger difference between MGuard and control in terms of rate of resolution of STEMI and percentage of patients achieving TIMI 3 flow than in earlier presentation, an effect that becomes more pronounced over time (see *Figure 5*).[22]

Figure 5: Efficacy of the MGuard Stent as a Function of Delay to Reperfusion in ST-elevation Myocardial Infarction – a MASTER Trial Substudy.



Source: Dudek et al., 2013[23]

In conclusion, Dr Dudek recommended that use of a mesh covered stent should be an important component of the decision-making process when a STEMI patient arrives in the catheterisation laboratory and that a combination of a DES, bioresorbable vascular scaffold and mesh covered stent would be desirable. ■

Preliminary Results From the iMOS Prime Registry International MGuard Prime Observational Study – Acute and 30-day Results

Giovanni Amoroso

Onze Lieve Vrouwe Gasthuis Hospital Amsterdam, The Netherlands

Dr Giovanni Amoroso, OLVG (The Netherlands) began by outlining the advantages of the MGuard Prime EPS, and then outlined a prospective, observational registry study whose objective was to evaluate the clinical performance of the MGuard Prime EPS in 'real world' STEMI patients undergoing primary PCI. Inclusion criteria was STEMI diagnosis with indication for primary PCI and reference vessel diameter of 2.75–4.0 mm. Exclusion criteria were cardiopulmonary resuscitation, cardiogenic shock, excessive tortuosity or calcification of the target vessel and side branches >2.0 mm. Baseline characteristics were similar to those in the MASTER trial,[3] with baseline TIMI flow of 0/1 in 71.6 % of patients. The mean symptom-to-balloon time was quite long: 237.8 min; most patients were preloaded with clopidogrel (94.8 %) and had undergone aspiration (74.2 %). Procedural success was 100%, without any problems of crossing the lesion or deploying the stent. TIMI flow of 3 was achieved in 91.8 % of patients and complete (>70 %) ST resolution in 76.1 %; these data are similar to those reported in the MASTER trial.[3] At 30 days, there was a low incidence of MACE (2.2 %), without any death.

In conclusion, this is the first report investigating the use of the MGuard Prime EPS in 'real world' patients. Results show that the MGuard Prime EPS has a good safety and efficacy profile. Twelve-month follow-up, to assess the impact on late MACE and clinical restenosis, is ongoing. ■

MASTER II – MGuard Prime Embolic Protection Stent

Jose Henriques

Academic Medical Center, Amsterdam, The Netherlands

Dr Jose Henriques, Academic Medical Center, (Amsterdam, The Netherlands) presented the Safety and Efficacy Study of MGuard Stent After a Heart Attack II (MASTER II) study. This aims to include 1100 patients with acute MI for >30 minutes and ≤ 12h from symptom onset with >2 mm ST elevation in ≥2 contiguous leads on baseline ECG. Exclusion criteria include left bundle branch block (LBBB), paced rhythm or other ECG abnormality interfering with assessment of ST-segment; current enrolment in another clinical trial that may interfere with the current study endpoint; a previous coronary interventional procedure of any kind within 30 days prior to the procedure; female patients of childbearing potential; subjects undergoing cardiopulmonary resuscitation; cardiogenic shock; the anticipated need for a staged procedure of a target vessel within 12 months or non-target vessel within seven days post-procedure; prior administration of thrombolytic therapy; comorbid conditions that might affect patient compliance with follow-up; concurrent medical condition with a life expectancy of <12 months and a history of cerebral vascular accident or transient ischaemic attack within the last six months or permanent neurological deficit. A wide variety of stents may be used as control.

After coronary angiography, and TIMI 2/3 has been achieved, patients are randomised to the MGuard Prime EPS or BMS/DES. Clinical follow-up is at 30 days, six months and 12 months. Extended follow-up is at two and three years. The primary endpoints are the rate of complete ST-segment resolution (>70 % resolution of the sum of ST elevations in all leads) within 60–90 minutes post-procedure, as well as a composite of all-cause mortality or recurrent target vessel MI at 365 days post-procedure.

Powered secondary endpoints include infarct size assessed by cardiac MRI in patients with anterior MI and proximal/mid LAD lesions, which is powered for superiority, and in-stent late lumen loss as measured by quantitative coronary angiography at 13 months; this is powered for non-inferiority. ■

Summary and Concluding Remarks

PCI is the optimal reperfusion modality in patients with acute STEMI and its use has resulted in improved survival in patients with cardiovascular disease. However, PCI often results in suboptimal myocardial perfusion due to embolisation of thrombus and atheromateous debris, which results in increased infarct size and mortality. The MGuard micronet mesh-covered stent prevents from distal embolisation and achieves excellent myocardial flow and complete resolution of ST-elevation, even in complicated clinical cases. The clinical trials and registry studies have provided a substantial body of evidence supporting the use of MGuard in primary PCI, with the objective of improving patient outcomes. Following the introduction on MGuard, treatment of acute MI has reached a new level involving a simple device that can be used in daily practice in the catheterisation laboratory. ■

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